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09/772,116	01/26/2001	Howard Benjamin	PPI-012CN	9135
959	7590	12/30/2003		
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			EXAMINER PONNALURI, PADMASHRI	
			ART UNIT 1639	PAPER NUMBER

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/772,116	Applicant(s) BENJAMIN ET AL.
	Examiner Padmashri Ponnaluri	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 September 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 9-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-7 and 9-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other:

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DETAILED ACTION

The amendment filed on 9/19/03 has been fully considered and entered into the application.

Claims 8, and 24-34 have been canceled by the amendment filed on 9/19/03.

Claims 1-7, and 9-23 are currently being examined in this application.

Applicants' amendment to the specification filed on 9/19/03 has been considered and would overcome the objections of record.

Withdrawn Rejections

The rejection of claims 4, 8, 9, 21 under 35 U.S.C 112, second paragraph (the maintained rejections have been addressed in the response to the arguments) have been withdrawn in view of the amendments and applicant's response.

The rejection of claim 21 under 35 U.S.C. 112, first paragraph has been withdrawn in view of applicant's response.

The obviousness type double patenting rejection of record ahs been withdrawn in view of abandonment of US patent application 08/769,250.

Maintained Rejections

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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2. Claims 1-23 are rejected under 35 USC. 112, second paragraph as being indefinite ("non-peptide") for the reasons set forth in the previous office action.
3. Claims 1, 3-4, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirshmann et al Blake for the reasons set forth in the previous office action.
4. Claims 1, 3-7, 9-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirshmann et al, Blake and Gordon et al for the reasons set forth in the previous office action.
5. Claims 1, -4, 9-12, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirshmann et al, Blake and Stankova et al for the reasons set forth in the previous office action.
6. Claims 1, 3-4, 8-12, 16-17, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirshmann et al, Blake, Stankova et al and Scott et al for the reasons set forth in the previous office action.

New Rejections Necessitated by the Amendment

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 1-7, 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The present claims are directed to a method for identifying a non-peptide compound that binds to a target, the method comprising: a) forming a first library of peptides; b) selecting from the first library at least one peptide that binds to the target; c) determining the amino acid sequence of the peptide; d) forming a second library comprising non-peptide compounds; e) selecting from the second library at least one non-peptide compound; f) determining the structure of at least one non-peptide compound; g) thereby identifying the non-peptide compounds that binds the target.

The specification description is directed to second library comprising analog library or the second library is synthesized based on altering D and L-amino acids; or the second library synthesized based on introduction of peptide mimetics at one or two positions within the library. The specification disclosure of second library comprising non-peptide compounds clearly do not provide an adequate representation regarding the open ended claimed non-peptide library compounds made and screened by the presently claimed invention. The instant claim non-peptide compounds would read on small organic molecule compounds which specification has no written support.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics regarding the non-peptide compounds of the second library.

Additionally, the narrow scope of examples directed to peptide analogs or peptidomimetic compounds with non-natural amino acids are clearly not representative of the scope of non-peptide compounds of the presently claimed invention.

3. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 9 recites ‘wherein step c) comprises determining the amino acid sequence or sequences of at least one peptide.’ Which is same scope as the independent claim step c).

Claim Rejections - 35 USC § 103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Baindur et al (US Patent 5,891,737).

The instant claims recite method for identifying a non-peptide compound that binds to a target, the method comprising: a) forming a first library of peptides; b) selecting from the first library at least one peptide that binds to the target; c) determining the amino acid sequence of the peptide; d) forming a second library comprising non-peptide compounds; e) selecting from the second library at least one non-peptide compound; f) determining the structure of at least one non-peptide compound; g) thereby identifying the non-peptide compounds that binds the target.

Baindur et al teach combinatorial non-peptide library . Baindur et al teach peptide libraries are source of small molecules having enormous structural diversity and can even larger conformational diversity. Active peptide identified through bioassay screening (refers to instant claim step b)) can be quickly optimized by synthesizing a large number of analogs (refers to instant claim step d)) by combinatorial and/or parallel robotic synthesis (e.g., see column 3, lines

1-3). The reference teaches that peptide libraries generated using heterochiral amino acids, all D-amino acids and non-proteinogenic amino acids represent a rich source that can be mined for stabilized peptide leads. The reference teaches that these peptide leads are readily developed into non-peptide or peptidomimetic lead compounds (refers to instant claim non-peptide compounds). The reference teaches solid phase synthesis of peptide analogues or peptidomimetics. The reference teaches that as the number of variables within each building block (monomeric units, or chemical groups) increase, and/or as the number of building blocks increase, the size of resultant library expands dramatically. Building blocks and monomers can be chemically conjugated to create a libraries containing components that are 100 to 1000 to 10,000 to 100,000 to 1,000,000 (and so on) building blocks in length (refers to instant claims 5-7).

The claimed invention differs from the prior art teaching by reciting ‘forming a first library (peptide library)’, and ‘determining the amino acid sequence of at least one peptide that binds the target’.

The reference teaches peptide libraries and methods of making the peptide libraries on solid support. The reference does not specifically teach the use of the synthesized peptide library in further manipulations. However, the reference gives general guidelines to make solid phase synthesis of peptide libraries. Thus, it would have been obvious to one skilled in the art at the time the invention was filed how to make peptide libraries and use the libraries to obtain analogs. The reference specifically has not taught determining the amino acid sequence of the active peptide. However, the reference teaches that the active peptide that binds to the target is identified, and the active peptide is optimized synthesizing a large number of analogs. Thus, the reference would require the amino acid sequence of active peptides such that analogs of the

peptides can be synthesized. The reference teaches the advantages of modified or analog peptides which are useful in therapy or diagnostics. Thus a person skilled in the art would have been motivated to make peptide libraries and use the active peptide from the library to prepare analogs which can be stabilized and useful in therapy. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference method. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed method is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

Response to Arguments

8. Applicant's arguments filed on 9/19/03, regarding 'non-peptide compounds as indefinite' have been fully considered but they are not persuasive.

Applicant's traverse the rejection and submit that the term 'non-peptide' is clear and definite when read in light of specification. Applicant's arguments have been considered and are not persuasive. The 'non-peptide' as in applicant's specification disclosure could only read on peptide derivatives or analogues wherein a single amino acid or few specific amino acids are replaced by synthetic or non-natural amino acids. However, the specification has not disclosed how many amino acids replaced and which amino acids were replaced, and further the term 'non-peptide' may read on small organic molecules which were not the peptide derivatives or

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peptide analogues or contain the non-natural amino acids, as in applicants disclosure. Thus, the metes and bounds of the term 'non-peptide' is not clear.

9. Applicant's arguments filed on 9/19/03, regarding the rejection of claims over Hirshmann et al and Blake et al have been fully considered but they are not persuasive.

Applicants argue that the instant claims are drawn to methods for identifying a non-peptide compound that binds to a target. The method involves forming a first library comprising multiplicity of peptides; selecting from the first library at least one peptide that binds to the target; determining the sequence of the at least one peptide thereby generating a peptide motif; forming a second library comprising non-peptide compounds designed based on the peptide motif; selecting from the second library at least one non-peptide compound that binds the target.

Applicants argue that Hirshmann et al teach methods for synthesizing steroidal peptidomimetics that are recognized by a target endocrine receptor. Hirshmann et al teach that "steroid molecules can serve as scaffold for the attachment of mimics". Hirshmann et al do not teach formation of libraries, nor do they teach or suggest methods of forming a first library comprising multiplicity of peptides.

Applicant's arguments have been considered and are not persuasive because Hirshmann et al teach non-peptide libraries of peptidomimetics based on known peptide motif. The rejection of record was based on combined teachings of Hirshmann et al and Blake et al.

Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Hirshmann et al teach methods of making non-peptide libraries

based on peptide motif, and methods of identifying the non-peptide which binds a target, and Blake teach methods of making peptide libraries and identifying a peptide which binds the target. Thus, it was well known in the art at the time the invention was made to methods for synthesizing peptide libraries and identifying a peptide which binds to a target, and the use the known peptide motif which binds to a target as a motif for the non-peptide libraries.

Applicant's further argue that Blake do not teach 'second library.' Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As discussed supra, in view of the combined teachings of Hirshmann et al and Blake, it would have been obvious to one skilled in the art at the time the invention was made to use the methods for making peptide libraries and screening the libraries for peptide (or a lead peptide) which binds to a target, and use the peptide in further non-peptide library synthesis.

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hirshmann et al teach non-peptide libraries based on a known peptide ligand; and Blake teach methods for synthesizing a peptide libraries, and identifying a peptide which binds to a target. Hirshmann et al teach methods for making non-peptide libraries based on peptide

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motif, which peptide motif could be a peptide identified from a peptide library, and further at the time the invention was made it was well known in the art methods for synthesizing peptide libraries and identifying a peptide which binds to a target (Blake). Thus it would have been obvious to one skilled in the art methods of identifying a peptide which binds to a target from a peptide library and further use the identified peptide in further libraries.

In response to applicant's argument that '*use of the claimed invention as described in the specification, allows for the identification of compounds that bind to a target that by use of peptide libraries with the use of the chemically based libraries such that advantage of each are maintained while the disadvantages of using either approach are overcome. The claimed invention has unexpectedly superior properties over the prior art because the skilled artisan can identify compounds that bind to a target by use of both peptide based and chemically based libraries, while maintaining the advantages of each,*' the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further it is not clear what are the advantages applicants are referring to which are different from the Hirshmann et al teachings. Hirshmann et al teach the known peptide motif which binds to a target and non-peptides which bind the target, thus the reference has compounds (peptide and non-peptide) which bind to the target. Applicant's arguments are not persuasive and the art rejections of record have been maintained for the reasons set forth in the previous office action.

11. Applicant's arguments filed on 9/19/03, regarding the rejection of claims over Hirshmann et al, Blake, and Gordon et al, have been fully considered but they are not persuasive.

Applicants argue that Hirshmann et al and Blake fail to teach the claimed method. Applicant's arguments have been considered and are not persuasive. Applicant's arguments regarding Hirshmann et al and Blake have been addressed supra.. Applicants further argue that Gordon et al teach methods for making peptide libraries and screening strategies, and Gordon et al do not teach or suggest methods for forming second libraries comprising non-peptide libraries based on peptide motif that is identified by screening a primary library. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus, it would have been obvious to one skilled in the art at the invention was made to form peptide libraries, and screen the library for a peptide which binds to a target as taught by Blake and use the known peptide(could be derived from a library) as basis for non-peptide libraries and screening them as taught by Hirshmann et al, and Gordon et al teach methods for making the specific size of the libraries.

12. Applicant's arguments filed on 9/19/03, regarding the rejection of claims over Hirshmann et al, Blake and Stankova et al have been fully considered but they are not persuasive.

Applicants argue that Hirshmann et al and Blake fail to teach the claimed method. Applicant's arguments have been considered and are not persuasive. Applicant's arguments regarding Hirshmann et al and Blake have been addressed supra.. Applicants further argue that Stankova et al disclose screening non-peptide libraries by mass spectroscopy but not disclosed forming a first library and selecting from the first library one peptide that binds to the target. This rejection was based on combined teachings of Hirshmann et al, Blake and Stankova et al. In

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response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Stankova et al teach the use of mass spectroscopy in analysis of structure of compounds identified in a library; Hirshmann et al teach methods of making non-peptide libraries and screening the libraries based on a known peptide motif(which binds to a target), and Blake teach the methods of making peptide libraries and methods of screening for a peptide which binds to a target. Thus, it would have been obvious to one skilled in the art at the invention was made to form peptide libraries, and screen the library for a peptide which binds to a target as taught by Blake and use the known peptide(could be derived from a library) as basis for non-peptide libraries and screening them as taught by Hirshmann et al and use tandem mass spectroscopy in identifying the structure of the non-peptide compounds as taught by Stankova et al.

13. Applicant's arguments filed on 9/19/03, regarding the rejection of claims over Hirshmann et al, Blake and Stankova et al and Scott et al have been fully considered but they are not persuasive.

Applicant's arguments have been considered and are not persuasive. Applicant's arguments regarding Hirshmann et al and Blake and Stankova et al have been addressed supra. Applicants further argue that Scott et al do not disclose forming a first library comprising multiplicity of peptides and use the peptide from the library in further methods of making non-peptide libraries. . Applicant's arguments have been considered and are not persuasive. Applicant's arguments against the references individually, one cannot show nonobviousness by

attacking references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The instant rejection was based on combined teachings of Hirshmann et al, Blake, Stankova et al and Scott et al. Hirshmann et al teach methods of making non-peptide libraries and screening the libraries based on a known peptide motif(which binds to a target), and Blake teach the methods of making peptide libraries and methods of screening for a peptide which binds to a target; Stankova et al teach the use of mass spectroscopy in analysis of structure of compounds identified in a library; and Scott et al teach methods of making peptide libraries on bacteriophages. Thus, it would have been obvious to one skilled in the art at the invention was made to form peptide libraries, and screen the library for a peptide which binds to a target as taught by Blake and use the known peptide(could be derived from a library) as basis for non-peptide libraries and screening them as taught by Hirshmann et al and use tandem mass spectroscopy in identifying the structure of the non-peptide compounds as taught by Stankova et al, and Scott et al the bacteriophage display peptide libraries.

Conclusion

No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
29 December 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER